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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,061	02/20/2007	Peisheng Cao	14556.0007USWO	7583

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EXAMINER
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LEITH, PATRICIA A

ART UNIT	PAPER NUMBER
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1655

MAIL DATE	DELIVERY MODE
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06/10/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/580,061	<b>Applicant(s)</b> CAO, PEISHENG	
	<b>Examiner</b> Patricia Leith	<b>Art Unit</b> 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-19 and 27-38 is/are pending in the application.
- 4a) Of the above claim(s) 8-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-7 and 27-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/9/09</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Claims 1-4, 6-19 and 27-38 are pending in the application.

### ***Election/Restrictions***

Claims 8-26 remain withdrawn from the merits as being directed toward a non-elected invention. See the election without traverse in the reply filed on 10/22/07 as well as the 'election by original presentation' as presented in the Office action dated 4/21/2008.

Applicant's election of 'plant product' in the reply filed on 12/21/09 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 27-38, newly added in the amendment filed by Applicant on 7/21/08 specifically narrow the method of claim 1 and thus are properly joined with claims 1-4 and 6-7 for examination.

Claims 1-4, 6-7 and 27-38 were examined on their merits.

### ***Claim Objections***

Claim 38 is objected to because of the following informalities: Claim 38 recites 'wherein the animal product or plant product comprises angelica.' First, Angelica is not an animal product and hence, referring to Angelica as an animal product is improper. Also, Angelica is referred to as 'angelica' in the claim. Angelica is the genus of the plant and therefore the first letter of Angelica should properly be capitalized. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1 and 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang (US 4,018,755) in view of Bloom (US 5,902, 224) in view of Kirker et al. (US 6,706,180). The rejection of claim 5 over Wang is evidenced by Soinneae, P. (1997)\*.

Wang (US 4,018,755) taught extraction of proteins from vegetable matter using sonication (nonlinear vibration) (see Abstract and Background, columns 1-2).

Wang discloses a specific example wherein 5 g of defatted soybean flakes obtained from cracking and dehulling (i.e., 'crushing') and solvent extraction were added to a jar with 50 ml (approximately 50 grams) of water, chilling the jar containing the defatted soybeans and water in an ice slurry and sonicating for 8 min., wherein the sonicator operated at a frequency of 20 KHz (nonlinear). The resulting mixture was centrifuged and the supernatant was recovered, yielding the soybean proteins (see Example 1, columns 2-3).

It is deemed that because the jar containing the water and the defatted soybeans was *chilled* in an ice slurry, that the temperature was within the Instantly claimed temperature range. It is deemed that the slurry would be about or colder than room temperature (18°C to 23 °C) but higher than freezing (0°C).

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As evidenced by Soinneae, P., soybean was a Chinese Traditional plant, from which medicines were obtained (see p. 59).

Wang did not specifically teach wherein the extraction occurred for 1 to approximately 3 hours, wherein the extraction temperature was 20 °C to approximately 50°C, wherein the extraction was under the pressure of 25~35 Mpa (megapascals) or wherein the ration of raw material to water was 1:3~5.

Centrifuges which operated at the claimed Mpa range were known in the art. For example, Bloom (US 5,902, 224) taught a centrifuge which operated between 2,300 and 5,000 psi ( ~15.9 Mpa to ~ 35 Mpa).

Kirker et al. (US 6,706,180) taught a system to create vibration in a centrifuge, wherein the vibration was anywhere between 100 to 40,000 Hz (see Entire reference, including the Abstract and col. 7, lines 18-27). Such a method, as explained by Kirker et al. provides a means for separating dense material from a fluid medium (see col. 2, line 44- col. 3, line 8).

Further, it is deemed that the centrifugation process as disclosed by Wang was part of the 'extraction' procedure, as this step separates the solid plant waste from the analyte supernatant. One of ordinary skill in the art would have been motivated to use a

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centrifuge such as the one disclosed by Bloom in order to centrifuge the extraction mixture of Wang because the centrifuge of Bloom was a conventional centrifuge known in the art at the time the Invention was made.

One of ordinary skill in the art would have been motivated to use vibration within the claimed frequency within the centrifuge as taught by Bloom in order to more fully separate the solid material from the liquid material upon plant extraction. It is clear from the references that vibration, in combination with centrifugal force which causes pressure within the claimed Mpa range, were known in the art. The ordinary artisan having the above-cited references before him or her would have had a reasonable expectation that the combination of method steps would have produced plant extracts since each step was known individually in the art.

Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A. While Wang did not specifically teach that the temperature of the extraction was 20 °C to approximately 50°C or wherein the ration of raw material to water was 1:3~5, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to determine all operable and optimal temperature conditions as well as solid/extraction liquid ratio as these are considered art-recognized result-effective variables which would have been routinely determined

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and optimized. Further, if there are any differences between Applicant's claimed method and that suggested by the combined teaching of the prior art, the differences would be appear minor in nature. Although the prior art did not specifically teach that the temperature of the extraction was 20 °C to approximately 50°C, one of ordinary skill in the art would have recognize that the proteins of Wang could have been extracted at room temperature, or at least a temperature below the denaturation temperature of the protein. While the prior art does not teach that the ratio of raw material to water was 1:3~5, it is deemed that the adjustment of solid material to extraction solvent is merely a matter of judicious selection, routinely adjusted in order to optimize yield of the analyte compound/active fraction of plant material.

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang (US 4,018,755) in view of Bloom (US 5,902, 224) in view of Yokotsuka et al. (US 4,064,277) in view of Kirker et al. (US 6,706,180). The rejection of claim 5 over Wang is evidenced by Soinneae, P. (1997).

The teachings of Wang and Bloom were discussed *supra*. These references did not specifically teach where the temperature of extraction was adjusted to the claimed range of 20 °C to approximately 50°C.



Yokotsuka et al. (US 4,064,277) taught that proteins were extracted from defatted soybeans at room temperature (see entire patent, especially Example 8, columns 8-9).

Again, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A. While Wang did not specifically teach that the temperature of the extraction was 20 °C to approximately 50°C it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to determine all operable and optimal temperature conditions as temperature is considered an art-recognized result-effective variable which would have been routinely determined and optimized. Although Wang did not specifically teach that the temperature of the extraction was 20 °C to approximately 50°C, because soybean proteins were known to be extracted at room temperature (approx. 18°C to 23 °C) one of ordinary skill in the art would have had a reasonable degree of success in carrying out the claimed method because the ordinary artisan would have recognized that the proteins of Wang could have been extracted at room temperature according to Yokotsuka et al.

Claims 1, 3-5 and 38 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over Wang (US 4,018,755) in view of Bloom (US 5,902, 224) in view of

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Kirker et al. (US 6,706,180) in view of Tao (US 2002/0009506 A1). The rejection of claim 5 over Wang is evidenced by Soinneae, P. (1997)\*.

The teachings of Wang, Bloom and Tao were discussed *supra*. None of these references specifically taught wherein Angelica was prepared by the method as Instantly claimed in claim 1.

Tao (US 2002/0009506 A1) taught that plant extracts suitable for enhancing brain function could have included Angelica extracts, and could have suitably been prepared via mixing via vibration (see entire reference, especially [0075]).

Applicants' arguments were fully considered, however, were not found persuasive.

Applicants' primary argument in traversal of this rejection set forth in the remarks filed on 3/30/2009 is that Applicants do not agree with the Examiner's broad interpretation of the term 'non linear vibration.' (p. 2, Remarks). Applicants compare the Examiner's interpretation of 'non-linear vibration' to that of considering 'curved' to be 'straight,' 'uneven' to be 'flat,' and 'moving' to be 'still.' (p. 2, Remarks of 3/30/09). Applicants quote In re Robertson:

To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference...that it would be so recognized by persons of ordinary skill. Inherency...may not be established by probabilities or possibilities. the mere fact that a certain thing may result from a given set of circumstances is not sufficient. " (p. 2, Remarks of 3/30/09).

However, the Examiner's interpretation of 'non-linear' is not unreasonable, and bears no similarity to Applicants' examples of 'curved' to 'straight' and 'uneven' to 'flat' for example. Applicants have not indicated that the vibration of a sonicator as cited by the prior art would not deliver a non-linear vibration and further have not further defined 'non-linear' in the specification or the claims to clearly delineate from vibration such as a vibration occurring from a sonicator as used by the prior art. The Examiner has provided a reasonable explanation of why one of ordinary skill in the art would consider the vibration oscillating from a sonicator would be non-linear. The Examiner has not provided an indication that non-linear vibration *might* occur in Wang who uses a sonicator to deliver vibrations to the soybeans, but rather, the Examiner has stated that non-linear vibrations *do occur* in any vibration. Applicants have not provided any evidence or convincing arguments to the contrary.

Applicants, in their response filed on 7/21/2008 argue that because the claim now states 'simultaneous conditions of a 18-33 kHz nonlinear vibration, a pressure of 25-35 Mpa and at a temperature of 0-50 °C, that the prior art does not render the claimed composition obvious (p. 10, Remarks of 7/21/2008).

However, the outstanding rejection made under 35 USC 103(a) is made in view of the combination of references, and not a single reference. While the prior art does explicitly teach wherein a plant extract was obtained via simultaneous conditions of 18-33 kHz nonlinear vibration, a pressure of 25-35 Mpa and at a temperature of 0-50 °C, Applicants have not set forth convincing arguments that subjecting the soybean slurry which was already chilled to a temperature within Applicants' claimed range to a centrifuge would not undergo vibration within this range, as centrifuges produce vibration in normal operation. Such vibrations would be non-linear.

At the time the Invention was made, extraction under the claimed conditions was known. Although the conditions may not have been known to occur simultaneously, it is determined that the ordinary artisan, having the understanding that pressure and vibration within the claimed ranges were used in the art for separating solid and liquid materials and that extraction materials were known to be chilled to temperatures within the claimed range would have been motivated to perform all of these conditions simultaneously with a reasonable expectation of success in producing a plant product.

The Supreme court has acknowledged that:

When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. **If a person of ordinary skill can implement a predictable variation..103 likely bars its patentability**...if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond that person's

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skill. A court must ask whether the improvement is more than the predictable use of prior-art elements according to their established functions...

**...the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results** (see *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 U.S. 2007) emphasis added.

[If]... there are [a] finite number of identified, predictable solutions, [a] person of ordinary skill in art has good reason to pursue known options within his or her technical grasp, and if this leads to anticipated success, it is likely product of ordinary skill and common sense, not innovation *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 U.S. 2007. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No Claims are allowed.

\*This reference is merely relied upon to state an inherent characteristic of soybean and is not used in the basis for rejection *per se*.

### ***Conclusion***

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Friday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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June 8, 2009